



Atty. Dkt. No. 029318-0596

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Ray W. WOOD et al.

Title: METHODS OF ADMINISTERING LIQUID DROPLET AEROSOLS OF NANOPARTICULATE DRUGS

Appl. No.: 09/577,489

Filing Date: 05/25/2000

Examiner: Qazi, Sabiha Naim

Art Unit: 1616

**TERMINAL DISCLAIMER FOR U.S. PATENT NO. 5,747,001**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Petitioner, Elan Pharma International Ltd., having its principal place of business at Wil House, Shannon Business Park, Shannon, Co. Clare, Ireland, represents that it is the owner of the entire right, title, and interest in and to U.S. Patent Application No. 09/577,489, filed on May 25, 2000, which is divisional of U.S. Patent Application No. 08/948,216, filed on October 9, 1997, now U.S. Patent No. 6,264,922, which is a continuation of U.S. Patent Application No. 08/589,681, filed on January 19, 1996, now abandoned, which is a continuation-in-part of U.S. Patent Application No. 08/394,103, filed on February 24, 1995. This application is owned by Elan Pharma International Ltd. by virtue of an Assignment from the inventors to Eastman Kodak Co. for Application No. 08/394,103 recorded on April 13, 1995, at Reel/Frame 007430/0713 (EXHIBIT 1); an Assignment from the inventors to Eastman Kodak Co. for Application No. 08/589,681 recorded on January 22, 1996, at Reel/Frame 007902/0485 (EXHIBIT 2); an assignment from Eastman Kodak Co. to Particulate Prospects Corp. recorded on February 20, 1996, at Reel/Frame 007820/0153-0159 (EXHIBIT 3); an assignment from Particulate Prospects Corp. to NanoSystems LLC recorded on February 20, 1996, at Reel/Frame 00817/0273-0279 (EXHIBIT 4); an assignment from

**RECEIVED**  
FEB 9 - 2004  
TECH CENTER 1600/2900

NanoSystems LLC to Elan Corporation plc recorded on May 5, 2000, at Reel/Frame 010797/0486-500 (EXHIBIT 5); and an assignment from Elan Corporation plc to Elan Pharma International Ltd. recorded on May 5, 2000, at Reel/Frame 010797/0501 in the United States Patent and Trademark Office (EXHIBIT 6).

Further, Petitioner represents that it is the owner of U.S. Patent No. 5,747,001 for "Aerosols Containing Beclomethasone Nanoparticle Dispersions," which issued on U.S. Patent Application No. 08/393,973, filed on February 24, 1995, by virtue of an Assignment from the inventors to Eastman Kodak Co. recorded on April 13, 1995, at Reel/Frame 007430/0698 (EXHIBIT 7); an assignment from Eastman Kodak Co. to Particulate Prospects Corp. recorded on February 20, 1996, at Reel/Frame 007820/0153-0159 (EXHIBIT 3); an assignment from Particulate Prospects Corp. to NanoSystems LLC recorded on February 20, 1996, at Reel/Frame 00817/0273-0279 (EXHIBIT 4); an assignment from NanoSystems LLC to Elan Corporation plc recorded on May 5, 2000, at Reel/Frame 010797/0486-500 (EXHIBIT 5); and an assignment from Elan Corporation plc to Elan Pharma International Ltd. recorded on May 5, 2000, at Reel/Frame 010797/0501 in the United States Patent and Trademark Office (EXHIBIT 6).

Petitioner respectfully disagrees with the Examiner regarding the obviousness-type double patenting rejection given in the Office Action dated January 21, 2004. This Terminal Disclaimer is being filed for the sole purpose of advancing the prosecution of this case.

Petitioner hereby disclaims the terminal part of the term of any patent granted on the above-identified patent application which would extend beyond the full statutory term of U.S. Patent No. 5,747,001. In addition, Petitioner hereby agrees that any patent so granted on the above-identified patent application shall be enforceable only for and during such period that the legal title to U.S. Patent No. 5,747,001 shall be the same as the legal title to any patent granted on the above identified patent application, this agreement to run with any patent granted on the above identified patent application and to be binding upon the grantee, its successors, or assigns.

In making this disclaimer, Petitioner does not disclaim any terminal part of any patent granted on the above identified patent application, prior to the full statutory term of U.S. Patent No. 5,747,001 as defined in 35 U.S.C. §§ 154-156 and 173, in the event that U.S.

Patent No. 5,747,001 expires for failure to pay a maintenance fee, is held unenforceable or is found invalid in a final judgment by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321(a), has all claims canceled by a reexamination certificate or as a result of an interference proceeding, or is otherwise not deemed to provide the rights conveyed by 35 U.S.C. § 154, prior to the full statutory term of U.S. Patent No. 5,747,001 as defined in 35 U.S.C. §§ 154-156 and 173, except for the separation of legal title stated above.

Further, Petitioner does not disclaim any terminal part of a patent granted on the above identified patent application that would extend beyond the present termination of U.S. Patent No. 5,747,001, in the event that such present term is extended by virtue of compliance with the conditions for term extension of any present or future patent term extension provisions of the patent law, including but not limited to 35 U.S.C. §§ 155, 155A, or 156, and without waiving Petitioner's right to extend the term of a patent granted on the above identified patent application to the extent provided by law.

The undersigned, being the Attorney of Record for the above identified patent application, and duly authorized to act on behalf of Petitioner, certifies that she has reviewed the Assignments attached as EXHIBITS 1-7, and to the best of her knowledge and belief, legal title to the above identified patent application and U.S. Patent No. 5,747,001 rests with Petitioner.

Atty. Dkt. No. 029318-0596  
Appln. No.: 09/577,489

The undersigned declares that all statements made herein of her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing therefrom.

Respectfully submitted,

Date Feb 4, 2004

By Michele M. Simkin

FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5109  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Attorney for Applicant  
Registration No. 34,717